UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

7590 06/02/2006

Richard M Klein
Fay Sharpe Fagan Minnich & McKee
1100 Superior Avenue Seventh Floor
Cleveland, OH 44114

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 10-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 10-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/20/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 33 contain the trademark/trade name Macrogol®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or

trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyethylene glycol and, accordingly, the identification/description is indefinite. Furthermore, it is noted that the trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4-7, 10-17, 24-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Dugger, III US 5,955,098.

Dugger discloses a soft bite gelatin capsule comprising a paste fill composition contains flavoring agent, sweetening agent, active compound, and excipient (see abstract, column 3, lines 12-62). Example 12 discloses a capsule fill comprising chocolate powder in an amount of about 46.67%, and nicotine (active agent) in an amount of 0.185%.

Regarding the limitation that the fill has been subjected to aging at a temperature of 30 to 40°C. It is noted that product-by-process claims are limited by and defined by the process. However, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). However, it is noted that Dugger teaches curing the filled capsule (column 3, lines 52-54), therefore, the aging is inherent.

Claims 1, 2, 12, 17 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. US 4,576,826.

Liu discloses a process for the preparation of flavorant capsule comprising obtaining a stable fill comprises tea, coffee, chocolate, and other flavor and/or aromatic principles, both natural and/or artificial (abstract; column 2, lines 5-32; and column 3,

lines 13-23). Liu further discloses the fill is kept under an advantageous temperature ranges from 0°C to 40°C (column 4, lines 11-20). Liu also discloses the obtained capsules are dried at room temperature over a period of time (column 6, lines 15-22).

Claims 1, 8, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Damour et al. US 5,563,144.

Damour discloses a capsule containing in addition to the active product, excipients such as cacao butter, glycerides or polyethylene glycol (column 12, lines 61-64). Active agent includes analgesic (column 3, lines 40-41).

Claims 1, 8, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nitardy US 2,206,113.

Nitardy discloses a composition comprising therapeutic agent, and melted fat filled into capsules to be chewed and swallowed (column 1, lines 1-15; and column 2, lines 13-16). Melted fat includes coconut oil, and cacao butter (Column 1, lines 16-33; and examples). Nitardy further teaches the melted fat is permitted to cool over a period of time to permit evaporation of solvent, and to obtain a solid mass (examples).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 10-17 and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl US 4,724,136 or Dugger, III US 5,955,098, in view of Borkan et al. US 4,935,243.

Dugger is relied upon for the reason stated above.

Scheibl teaches a confectionery preparation in the form of chewable capsules, tablets, chewing gums, wafer and the like comprising a fill material comprises cacao powder, flavoring, and coloring agents (abstract; column 1, lines 30-55; and example 1). The fill further comprises drugs or active agents (column 2, lines 51-65).

Scheibl or Dugger does not explicitly teach the capsule shell as claimed in claim 19. However Dugger incorporates Borkan by reference for the teaching of chewable soft gelatin capsule.

Borkan teaches a chewable, edible soft gelatin capsule comprising a solid or semi-solid fill material (see abstract; and column 3, lines 1-5). The gelatin shell comprises gelatin, glycerin as a plasticizer, D-sorbitol, and sweetener (columns 3-4; and column 5, lines 1-36). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable, edible soft gelatin capsule of Borkan to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claims 1, 2, 4-7, 10-17 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Ebert et al. US 4,532,126.

Scheibl or Dugger, III is relied upon for the reason stated above. Neither Scheibl nor Dugger explicitly teach the capsule shell as claimed in claim 19.

Ebert teaches a chewable soft gelatin capsule comprising gelatin, water, a plasticizer and a masticatory substance (Col. 54-68). The plasticizer is glycerin or sorbitol (Col. 2, lines 54-60). The capsule is filled with candy confectionaries, antacids, cough preparations, cold preparations, sore throat remedies, antiseptics, dental preparations, dextromethorphan, and/or acetaminophen (Col. 3, line 67 - Col. 4, line 3; Col, 5; Example 11; Col. 6, Example IV). The capsules also contain taste modifiers or flavoring agents (Col. 4,lines 1 3-25). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable soft gelatin capsule of Ebert to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III or Nitardi, in view of Ebert et al. US 4,532,126.

Scheibl, Dugger or Nitardi is relied upon for the reasons stated above. The cited references do not teach aging the fill material.

Regarding the process claims 29 and 30, Ebert teaches drying the freshly made capsule for a suitable length of time until the desired chewing characteristics are attained (see abstract; column 2, lines 46-54; column 4, lines 37-41; and examples). Ebert does not explicitly teach the drying temperature at 30 to 40°C. However, drying can be at room temperature which falls within the claimed range, see Sacripante at

column 7, lines 66-67, which teaches room temperature is from about 20°C to about 40°C; or Takegawa at page 2, lines 24-25, which teaches room temperature is in a range of 0°C to 40°C. Thus, it would have been obvious to one of ordinary skill in the art to, dry the capsule taught by Scheibl, Dugger or Nitardy in view of the teaching of Ebert, because Ebert teaches capsules are dried to obtain a desired chewing characteristics (id), because Dugger teaches curing the capsules, because Scheibl teaches capsule filled with cacao powder that has superior taste, and because Nitardy teaches cooling the melted fat to obtain a solid mass.

Claims 8 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Perry et al. EP 0 904 064 and Miyake et al. US 4,219,439.

Dugger and Scheibl are relied upon for the reasons stated above. Dugger or Scheibl does not expressly teach the use of the filled material claimed in claim 8.

Perry teaches an oral pharmaceutical composition to be filled into capsules comprising digestible oil in the carrier including coconut oil, polyethylene glycol, and surfactant such as castor oil (paragraphs 0019-0020). Miyake teaches oil includes lard, castor, soybean, combination thereof, and the like (column 4, lines 3-10). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Dugger or Scheibl using the additives in view of the teachings of Perry and Miyake, because Perry teaches the use of digestible oil to provide good solubilisation to employ a smaller capsule size to deliver the same drug does compared with similar formulations in the

prior art, and because Miyake teaches the equivalency between lard and other digestible oils.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Mehta US 5,084,278.

Neither Scheibl nor Dugger does teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to use chocolate flavor as the flavoring agent for the fill material taught by Scheibl or Dugger, because the references teach the use of flavoring agent suitable for taste masking of active agents acceptable for chewing composition.

Response to Arguments

Applicant's arguments filed 03/20/06 have been fully considered but they are not persuasive.

Applicant argues that the Examiner's reasoning may be incorrect because it applies Applicant's definition of "room temperature" to the references when the references do not give this definition. In response to applicant's argument, Sacripante et al. and Takegawa et al. are cited for the teachings of room temperature of up to 40°C.

Applicant argues that applicant is unable to find in the cited references a teaching for suggestion to age the fill material above room temperature. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., aging the fill material above room temperature) is not recited in the rejected claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This argument is confirmed in view of the teachings of Sacripante at column 7, lines 66-67, wherein room temperature is from about 20°C to about 40°C; or Takegawa at page 2, lines 24-25, wherein room temperature is in a range of 0°C to 40°C.

Applicant argues that Ebert discloses the capsule is dried, not the fill material. Applicant further emphasized that the step of aging the fill material is distinct from the step of drying the capsule, and the specification describes both steps separately. In response to applicant's argument, the examiner is unable to determine the distinct between the two steps. Applicant's attention is called to the instant specification at pages 19-20, which describes *the process of production of the soft capsule of the present invention comprising melting the chocolate base, mixing drug (or food) and other excipients to the melted chocolate base while heating to obtain a fill material as a uniform suspension. Separately a shell material is prepared, and the shell is filled with the fill material. After filling the capsule, optionally followed by drying in a drying chamber whose temperature is controlled. This drying step is continued at a desired temperature for a predetermined time or more so that the fill material can experience an*

aging effect. Accordingly, the teaching of drying the filled capsule in Ebert would be inherent and obvious the claimed aging step.

Applicant argues that the teaching of Borkan, Ebert, and Mehta that the capsules have superior taste does not mean they achieve their superior taste in the same way as the instant application. This statement has not been supported by any Declaration showing that the superior taste taught by the cited references is detrimentally different from the claimed invention.

Applicant argues that none of the cited references have the process step which leads to this structural difference and the Examiner has not shown where any of the references discloses that it has the structural difference. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., structural difference) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner is unable to determine the unexpected results over the structural differences. Applicant has not shown that the structural different would result in a detrimental effect in the desirability of obtaining capsules having superior taste.

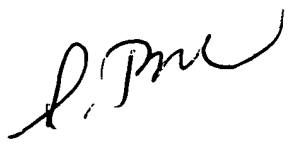
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-

0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran
Patent Examiner
Art Unit 1615